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Proposed Maximum Residue Limit PMRL2014-37

Spinosad

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on various vegetables to the product labels of Success 480 SC Naturalyte Insect Control Product and/or Entrust 80 W Naturalyte Insect Control Product, both containing technical grade spinosad, is acceptable. The specific uses approved in Canada are detailed on the labels of Success 480 SC Naturalyte Insect Control Product and Entrust 80 W Naturalyte Insect Control Product, Pest Control Products Act Registration Numbers 26835 and 27825, respectively.

The evaluation of these spinosad applications indicated that the end-use products have merit and value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for spinosad is being conducted via this document (see Next Steps, the last section of this document). Details regarding the registration for asparagus, green onions and leaf lettuce can be found in the corresponding Evaluation Report available in the Pesticide and Pest Management section of Health Canada's website, under Public Registry, Pesticide Product Information Database.[1] A summary of the field trial data used to support the remaining proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to replace or be added to the MRLs already established for spinosad, are as follows.

[1] The relevant report can be accessed by selecting Applications/Minor Use/Historical and requesting the Evaluation Report found under Application Numbers 2009-4163 (Success), 2011-0987 (Success), 2011-0984 (Entrust).

Table 1 Proposed Maximum Residue Limits for Spinosad

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Spinosad	Spinosyn A: (2*R*,3a*S*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-L-mannopyranosyl) oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)-tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1*H*-as-indaceno[3,2-d]oxacyclododecin-7,15-dione and Spinosyn D: (2*S*,3a*R*,5a*S*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-L-mannopyranosyl) oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino)-tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1*H*-as-indaceno[3,2-d]oxacyclododecin-7,15-dione	25	Leaf lettuce[2]
		0.1	Bulb Onion Subgroup (Crop Subgroup 3-07A)
		0.1	Green Onion Subgroup (Crop Subgroup 3-07B)
		0.02	Asparagus

1 ppm = parts per million

2 The MRL is proposed to replace the currently established 7.0 ppm MRL for leaf lettuce due to the addition of greenhouse lettuce production to the registered use pattern. The 7.0 ppm MRL established for head lettuce remains in effect.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for spinosad in Canada with corresponding American tolerances and Codex MRLs[2]. American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Leaf lettuce	25	8.0 (Vegetable, leafy, except brassica, group 4)	10 (Leafy vegetables)
Bulb Onion Subgroup (Crop Subgroup 3-07A)	0.1	0.1 (Vegetable, bulb, group 3, except green onion)	0.1 (Onion, bulb)
Green Onion Subgroup (Crop Subgroup 3-07B)	0.1	2.0 (Onion, green)	4 (Spring onion)
Asparagus	0.02	0.2 (Asparagus)	Not established

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for spinosad up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

[2] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed MRLs for Bulb Vegetables

Residue data from field trials conducted in Canada were submitted to support the domestic use of Success 480 SC Naturalyte Insect Control Product and Entrust 80 W Naturalyte Insect Control Product on Bulb vegetables group (Crop Group 3). Spinosad was applied to dry bulb onions at the proposed rate, and crops were harvested according to the proposed label directions. Previously reviewed residue data from field trials conducted in/on green onions were reassessed in the framework of this petition.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for spinosad was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs.

Table A1. Summary of Field Trial Used to Support Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	Preharvest Interval (days)	Residues (ppm)	
			Min	Max
Dry bulb onions	Foliar broadcast ground application/ 297-340	3-4	<0.02	<0.04

Following the review of all available data, an MRL of 0.10 ppm is recommended to cover residues of spinosad in/on commodities of Crop Subgroup 3-07A. Residues of spinosad in these crops at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.